III. REMARKS/ARGUMENTS

The undersigned gratefully acknowledges the courtesies extended by Examiner Barts during the interview conducted on December 14, 2004.

A. Status of the Claims

Claims 1 and 42-51 and 63-78 are pending. Claims 1 and 42-45 have been amended without prejudice. Claims 52-62 have been cancelled without prejudice. New claims 63-78 have been added. Support for the current amendments can be found in the original specification as filed, e.g., at page 6, lines 6-7 and 18-20 and page 8, lines 17-21. In is respectfully submitted that no new matter has been added by virtue of the present amendment.

The amendments to the claims are made without prejudice to the further prosecution of the pending claims in a continuation application.

B. Statement of Substance of Interview

During the Interview of December 14, 2004, all of the pending claims were discussed and the Applicants maintained their position that the cited prior art does not motivate one skilled in the art to provide a 24 hour tramadol formulation. It was argued that the Examiner's position with respect to the cited prior art is an impermissible "obvious to try" argument.

C. Rejection Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 1 and 42-62 under 35 U.S.C. § 103(a) as being unpatentable over Raffa *et al.* ((Caplus 1992:120745, J. Pharmacol. Exp. Ther. 1992, 260 (1), 275-85)) in view of EP 0147780 to Bondi ("the Bondi reference"). The Examiner's rejection was based on his previous Office Actions dated April 4, 2002, January 14, 2003 and October 21, 2003.

As argued during the Interview, Applicants maintain their position that the claims are patentable over the cited prior art. However, in order to advance the prosecution of the present application, claim 1 has been amended without prejudice to recite as follows:

> *A solid controlled release oral dosage form, comprising,*
> *a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a normal release matrix,*
> *said matrix overcoated with a controlled release coating comprising a polymethacrylate or a water insoluble cellulose,*
> *said dosage form providing a therapeutic effect for at least about 24 hours*
> (Emphasis added)

It is respectfully submitted that the Bondi reference is directed to controlled release dosage forms utilizing polyvinyl alcohol as the controlled release material. The present claims recite a "... controlled release coating comprising a polymethacrylate or a water insoluble cellulose..." which is neither taught nor suggested by the Bondi reference. Therefore, a combination of Raffa et al. with the Bondi reference would not teach or suggest a dosage form comprising a "... controlled release coating comprising a polymethacrylate or a water insoluble cellulose..."

Accordingly, the Examiner is requested to remove the rejection under 35 U.S.C. § 103(a) over Raffa et al. in view of the Bondi reference.

D. CONCLUSION

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn. It is believed that all claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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